

MANUFACTURING EXTENSION PARTNERSHIP

Success Stories from the Field

First Quality Hygienic Inc

Mid-Pennsylvania Manufacturing Extension Partnership

First Quality Hygienic Obtains Quality Certifications To Remain Globally Competitive

Client Profile:

First Quality Hygienic, Inc. is a leading manufacturer of feminine hygiene products and markets Femtex® brand tampons to retailers throughout the United States. First Quality is also the leading private label manufacturer for some of the largest retailers in the world. Located in McElhattan, Pennsylvania, the company employs less than 500 people.

Situation:

To continue selling tampons in Canadian markets, First Quality Hygienic (FQH) needed to obtain certification to ISO 9001:1994, ISO 13485:1996, and CMSCAS (Canadian) quality standards for medical devices. The company needed to be certified to each standard by December 31, 2002 to meet the Canadian deadline. FQH called in the Industrial Manufacturing Center (IMC), a NIST MEP network affiliate and division of the Mid-Pennsylvania Manufacturing Extension Partnership, for assistance.

Solution:

IMC provided analysis, training, and consultation to FQH and its employees. Every FQH employee participated in IMC-administered quality awareness (for ISO 9001 and 13485) and audit training. Selected employees received additional training in internal auditing and process mapping. IMC also helped FQH locate a trainer who could present specialized risk analysis training in hazard analysis and critical control point (HACCP). In addition to its original assessment of the FQH quality management system, IMC conducted a final gap analysis prior to the registrar's pre-audit, and helped FQH select an appropriate auditor.

FQH successfully passed the registrar's final audit and achieved certification to ISO 9001:1994, ISO 13485:1996, and CMSCAS on November 22, 2002.

Results:

Achieved ISO 9001:1994, ISO 13485:1996, and CMSCAS certification well before deadline.

Retained 100 percent of sales in Canadian market.

Positioned for new growth in markets that require quality certifications.

Improved product quality.

Testimonial:

www.mep.nist.gov



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"IMC, a division of Mid-Pennsylvania Manufacturing Extension Partnership, provided FQH with significant help in achieving the goal of ISO certification. FQH was charged with meeting this challenge within a 12-month period, or potentially see a significant impact in sales. We not only achieved our goal of ISO certification, but also have seen a continuing improvement in FQH operations."

Mark Loewen, Director, Quality Assurance/Regulatory Affairs